IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CADENCE PHARMACEUTICALS, INC. and SCR PHARMATOP,	)	
Plaintiffs,	)	
vs.	)	C.A. No. 11-733-LPS
EXELA PHARMA SCIENCES, LLC; *et al.*,	)	**REDACTED - PUBLIC VERSION**
Defendants.	)	

DEFENDANTS' RESPONSE TO PLAINTIFFS' LETTER TO THE HONORABLE LEONARD P. STARK (D.I. 299)

Dear Judge Stark:

Defendants Exela Pharma Sciences, LLC, Exela PharmSci, Inc., and Exela Holdings, Inc. (collectively "Exela") hereby respond to Plaintiffs' motion (D.I. 299) requesting sanctions, a continuance of the pre-trial and trial schedules in this action, and permission to proceed with the Drouin deposition prior to the French Authority acting on Exela's request for International Judicial Assistance (the "Request"). As detailed herein, Plaintiffs' motion is based on factual inaccuracies and is not supported by the law. Therefore, the motion should be denied.

Exela has not violated its discovery obligations

In regards to the exclusionary sanction sought by Plaintiffs, "[i]t bears emphasis that exclusion of 'critical evidence,' such as an expert report on infringement, is an 'extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence.'" *B. Braun Mensungen AG v. Terumo Medical Corp*., 749 F. Supp. 2d 210, 221 (D. Del. 2010). Plaintiffs identify no violation by Exela of any disclosure required by Rule 26, nor have they shown any willful deception or flagrant disregard of any orders. Rather, Plaintiffs simply complain that Exela should have—during fact discovery—disclosed tests performed only for Exela's expert after fact discovery closed, under his supervision and direction, and in connection with preparing his rebuttal expert report. Plaintiffs' arguments lack merit for at least two reasons.

First, Exela timely submitted its expert reports and supporting data as required by Rule 26(a)(2)(B). All testing data relied upon by Exela's expert was created after receipt of Plaintiffs' expert reports, and was specifically created, under Exela's expert's supervision and direction, to rebut the opinions of Plaintiffs' experts. Thus, Plaintiffs statement that Exela misled the Court simply is false. *See* D.I. 299 at 1 (erroneously stating that "[t]his new proffer even contradicts Exela's direct representations to the Court that such evidence was '*nonexistent*'"). Before receipt of Plaintiffs' expert reports, Exela had no dissolved oxygen testing data in its possession, custody or control that it could disclose during fact discovery because Exela performed no such testing. Exela is aware of no authority, and Plaintiffs' cite none, requiring Exela to create data to be used by its expert (or by Plaintiffs' experts) during fact discovery. Rather, Rule 26(a)(2)(B) plainly states that data supporting expert testimony must be disclosed with the expert report, not before as argued by Plaintiffs in their motion.

Consistent with the Court's Amended Scheduling Order (D.I. 292), Exela served the rebuttal report of Dr. Anthony Palmieri on February 22, 2013, which included test data on the measured dissolved oxygen content at various points during Exela's process. That testing was performed on February 12, 2013—18 days *after* Exela received Plaintiffs' initial expert reports on infringement. Before receiving Plaintiffs' expert reports, Exela conducted no dissolved oxygen testing other than measuring the dissolved oxygen content in November 2010 for Lot Number XLNL1021 that was submitted to the FDA.

Exela did not perform any dissolved oxygen testing beyond that done in November 2010 because the only relevant claim in the `218 patent, claim 1, requires "**deoxygenation of the solution by bubbling with at least one inert gas** and/or placing under vacuum, **until the oxygen content is below 2 ppm**." (Emphasis Added). '218 patent, claim 1 (emphasis added). Exela designed its process to avoid the `218 patent by ensuring that [redacted]

[redacted] *See, e.g.*, Ex. A, (Exela's batch record) at EXELA-00000727.

Exela's batch record also instructs the operator to [redacted] Ex. A at EXELA-00000728 [redacted] (emphasis added). Accordingly, until February 12, 2013, when Exela's expert supervised and directed the measurement of the dissolved oxygen content during the accused process, there was nothing to disclose. Not disclosing something that did not exist cannot be a violation of Fed. R. Civ. P. 26(a)(1).

During fact discovery, Plaintiffs sought to inspect Exela's facility. Ex. B (Plaintiffs Request for Entry Upon Land for Inspection and Other Purposes Pursuant to F.R.C.P. 34(a)(2)). Exela objected to the inspection, in part, because the request was overly broad and invasive. For example, the request sought to inspect nearly every piece of equipment in Exela's facility even if unrelated to the claims and defenses in the case. Exela also believed that the information sought by Plaintiffs could be readily obtained from other sources, such as Exela's batch record.

Nearly two months after Exela's objections to the requested site inspection, Plaintiffs clarified that they were seeking, for example, information on "the specific method that [Exela] uses to test dissolved oxygen levels, [redacted]" Ex. C (Aug. 21, 2012 Letter from M. Zubick to L. Peterson). That information, however, was readily available from documents already produced, including Exela's batch record. *See, e.g.*, Ex. A. Notably, Plaintiffs never requested to enter Exela's facility for purposes of testing the dissolved oxygen levels at specific points during a run of Exela's process. Ex. B & C.

Based on the parties' discussions about the site inspection, it was apparent that the information that Plaintiffs were seeking was available from Exela's batch record. Indeed, Plaintiffs never moved to compel a site inspection. Thus, Plaintiffs inaccurately claim that Exela provided information to its expert that it should have provided to Plaintiffs. Moreover, Plaintiffs have had Exela's batch record, which details its manufacturing process, since the very beginning of this case and thus their experts could have performed the process themselves. Apparently, Plaintiffs' experts did not perform the process set forth in Exela's batch record.

On January 25, 2013, Plaintiffs served the expert report of Dr. Martin Schoonen. Dr. Schoonen's expert report is directed to Plaintiffs' infringement theory that [redacted] meets the "bubbling" limitation of the '218 patent. His opinions, however, were not based on any measurements taken while performing the process, but instead based on theoretical calculations. In response to Dr. Schoonen's expert report, Exela's expert, Dr. Palmieri, supervised and directed the preparation of Exela's product in accordance with the manufacturing process set forth in the batch records and measuring the dissolved oxygen content

at various points of the process. This testing has become known as the "Batch 2" testing.[1] The Batch 2 testing was recorded in a batch record submitted with Dr. Palmieri's report and produced to Plaintiffs – only 10 days *after* the tests were performed.

Upon Plaintiffs' request, Exela agreed to a site inspection so that Plaintiffs' counsel and experts may observe the same process and take the same dissolved oxygen measurements that Dr. Palmieri supervised and directed. Exela also agreed to a 30(b)(6) deposition directed to the process that was run under Dr. Palmieri's supervision and direction. The parties also agreed to extend the reply report deadline by 10 days, which would still have allowed sufficient time to complete expert depositions prior to the April 5, 2013 deadline. Despite Exela providing Cadence with full disclosure of the Batch 2 testing performed by Dr. Palmieri, Plaintiffs chose to forgo the inspection and deposition, and instead filed the present motion for sanctions.

Exela can find no legal authority, and Plaintiffs cite none, holding that expert testing must be disclosed during fact discovery. To the contrary, courts have held that expert testing are generally not discoverable unless and until a decision has been made to use the tests at trial. *See U.S. v. Dentsply Int'l, Inc.*, C.A. No. 99-5-MMS, 2000 WL 654378, at *5 (D. Del. May 10, 2000); *see also Karan v. Nabisco, Inc.*, 82 F.R.D. 683, 685-86 (W.D. Pa. 1979) holding that a party was not required to disclose survey material prior to deciding whether it would use the survey at trial). This is especially true in this case when the Batch 2 tests were not even conducted until after fact discovery closed and the parties were in the midst of expert disclosures. For these reasons alone, Plaintiffs' motion must be denied.

Second, Plaintiffs' own conduct establishes that expert testing does not need to be disclosed until expert disclosures. For example, during fact discovery, Exela requested production of "[a]ll documents that refer or relate to allegations in Plaintiffs' Complaint that Defendants have infringed the '218 patent." Ex. D. (Exela RFP No. 32). Subject to certain objections, Plaintiffs agreed to produce "responsive, non-privileged documents in its possession, custody or control to the extent that such documents exist and are located after a reasonable search." Ex. E (Plaintiffs' responses to RFP No. 32). On or about July 27, 2012, Plaintiffs' expert, Dr. Park, tested the dissolved oxygen content of product samples provided by Exela. The test procedures and results were recorded in a lab notebook, which was attached to Dr. Park's expert report as Exhibit C. That lab notebook is dated July 27, 2012, nearly five months before the close of fact discovery. Ex. F. Despite Exela's outstanding discovery requests specifically covering this information, Plaintiffs never produced Dr. Park's test data until service of their expert reports and the test data was never identified on a privilege log. Drs. Orr and Schoonen relied on the Park test data in rendering their opinions.

Similarly, Exela also requested production of "[a]ll buffering agent studies, tests, or evaluations" relating to the '222 patent. *See, e.g.*, Ex. G (Exela RFP No. 4). Subject to certain objections, Plaintiffs agreed to produce "responsive, non-privileged documents in its possession,

[1] The Batch 2 testing was performed solely for purposes of this litigation in connection with Dr. Palmieri's expert report. It is purely experimental and cannot be used for any commercial purpose. In fact, the Batch 2 record (D.I. 299, Ex. N) shows [redacted]

custody or control to the extent that such documents exist and are located after a reasonable search." Ex. H (Plaintiffs' responses to RFP No. 4). On or about November 8, 2012, another of Plaintiffs' experts, Dr. Yeo, performed studies seemingly intended to prove that [redacted] as the claimed buffering agent in claim 1 of the `222 patent. Dr. Yeo memorialized these studies in a lab notebook dated November 8, 2012, which is over a month before the close of fact discovery. Ex. I. Yet again, Plaintiffs never disclosed this testing, despite discovery requests specifically directed to this information, until service of their expert reports. This testing was also not identified on a privilege log. Dr. Orr relied upon the Yeo test data in rendering his opinions.

Plaintiffs' decision to not disclose the Park and Yeo tests during fact discovery shows that Plaintiffs, like Exela, never expected that expert testing needed to be disclosed during fact discovery. However, if Plaintiffs are correct that expert tests must be disclosed during fact discovery, then the expert reports of Drs. Park, Orr, and Schoonen would also have to be excluded under Plaintiffs' reasoning. Indeed, under Plaintiffs' theory, every expert report submitted in this case on the issue of infringement, including their own, should be excluded. That would be an absurd result not supported by the facts or the law.

Plaintiffs' arguments of prejudice also are not persuasive.[2] Expert discovery remains open, and expert depositions have not yet been scheduled. Once scheduled, Plaintiffs will be able to question Dr. Palmieri on his opinions and the dissolved oxygen test data. Indeed, any purported prejudice to Plaintiffs is self-imposed. As noted above, Plaintiffs requested, and Exela agreed, to allow Plaintiffs' experts and counsel to observe the same process that was performed under Dr. Palmieri's supervision and direction at Exela's facility. Exela also agreed to allow Plaintiffs a 30(b)(6) deposition directed to the process observed by Dr. Palmieri. The parties also agreed to move the reply expert report deadline by 10 days after the inspection, which is more time than Dr. Palmieri had from the date of the Batch 2 testing to when Exela served Dr. Palmieri's rebuttal expert report, and would have still provided the parties more than enough time to complete expert depositions before the April 5 deadline. A few days before the deposition and inspection were to occur, Plaintiffs unilaterally cancelled their inspection, relying on the excuse that Exela had not provided discovery related to the Batch 2 testing. Their motion for sanctions quickly followed their cancellation of the inspection.[3] These facts do not warrant the extreme" sanction of the exclusion of evidence. *Quinn v. Consol. Freightways Corp. of Del.*, 283 F. 3d 572, 577 (3rd Cir. 2001).

For the foregoing reasons, Plaintiffs' request for preclusion sanctions must be denied.

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[2] Plaintiffs' claim that they must subject the samples provided by Exela to at least 3 months of stability testing also rings hollow. The stability of Exela's product is not in dispute as evidenced by the fact that none of Plaintiffs' experts submitted an expert report on this topic.

[3] It should be noted that Plaintiffs requested that Exela provide response to new discovery requests and supplement its responses to some interrogatories on or before March 12, 2013, one week after it served its request. Without even waiting for their own unilaterally set deadline for Exela to respond to pass, Plaintiffs demanded that Exela respond immediately and then proceeded to file this motion for sanctions.

Exela has diligently sought an Order from the French authority and documents from BMS

Plaintiffs contend that the Drouin deposition is relevant to commercial success because Mr. Drouin will provide testimony regarding foreign sales. Plaintiffs seek this testimony in an attempt to establish commercial success because their product, Ofirmev, has not been commercially successful in the United States.[4] Exela disputes the value of Mr. Drouin's expected testimony but if Plaintiffs nonetheless insist on deposing Mr. Drouin, then Exela must have access to and be able to use at the deposition the very documents that would either support or rebut Mr. Drouin's testimony. The Court recognized this issue during the November 9 hearing and questioned the value of Mr. Drouin's testimony without the supporting documentation requested by Defendants. D.I. 299, Ex. P at 8, 13. Despite the Court's instructions, Plaintiffs have sought to preclude Exela from obtaining such documentation.

Plaintiffs wrongly assert that Exela has failed to act diligently in its efforts to obtain an Order from the French Authority. In reality, Exela has not delayed or in any way created a "stalemate" warranting Plaintiffs' requested relief. Plaintiffs mischaracterize Exela's efforts, suggesting that Exela delayed submitting its Request for two months after the Court's November 9 hearing. On the contrary, Exela has done and continues to do everything in its power to obtain the Order and the requested documents from Bristol-Myers Squibb Co. in New York ("BMS US") pursuant to Exela's subpoena. D.I. 77. Moreover, Plaintiffs conveniently ignore the fact that they have a contractual right to obtain the discovery Exela seeks from BMS in France. Notwithstanding this contractual right, Plaintiffs have refused to obtain those documents on their own, despite the information being responsive to several outstanding discovery requests served by Exela on Plaintiffs. Again, any delay or harm from those documents not being produced is self-inflicted from Plaintiffs' own contractual inaction.

Regarding Exela's efforts to execute the Request, and as Exela previously explained to Plaintiffs, the original Request issued by this Court on November 14, 2012, was overseen by Exela's co-defendants—Paddock Laboratories, Inc., Perrigo Company, and Paddock Laboratories, LLC (collectively, "Paddock"). Plaintiffs are well aware of this fact, as evidenced by the Request itself which directs the French Authority to return the executed Request to Paddock's counsel. D.I. 271 at 271-1, p.2. Unbeknownst to Exela, during this time Paddock was actively engaged in settlement negotiations with Plaintiffs. Presumably, as a result of those negotiations, Paddock seemingly never had the Request translated into French and did not submit the Request to the French Authority.[5] Paddock subsequently settled with Plaintiffs and was

[4] Indeed, Plaintiffs did not submit an expert report to show commercial success in the United States, or any other secondary consideration of nonobviousness, despite the fact that such reports were due on February 22, 2013.

[5] Exela has never claimed that Paddock blocked Exela from receiving a translation of the Request. Rather, Exela explained to Plaintiffs that Paddock was overseeing the submission of the Request to the French Authority, and Exela assumed, until Paddock was dismissed from the case and it learned otherwise, that Paddock had submitted the Request. As further evidence of Defendants' respective roles regarding BMS discovery, at the November 9 hearing, Paddock's counsel argued in support of Defendants' Request, with counsel for Exela only relaying

dismissed from this case on November 29, 2012. To the extent Cadence became aware through its negotiations with Paddock that the Request was not moving forward, it declined to share that information with Exela. Upon learning that Paddock had discontinued its efforts to obtain approval of the Request, Exela moved diligently to obtain such approval.

Plaintiffs' counsel contacted Exela's counsel after the French Authority requested that the Orders contain the appointment of a commissioner to oversee the taking of evidence. On December 5, 2012, Plaintiffs filed a letter on behalf of all parties requesting that the Court issue an Order appointing Denis Chemla as commissioner. D.I. 279. Plaintiffs' letter also explained that because Paddock had been dismissed from the case, Exela would take over efforts regarding Defendants' Request. *Id.* Plaintiffs' letter asked the Court to reissue Defendants' Request designating Exela as Defendants' U.S. representative. *Id.* Last, Plaintiffs' letter asked the Court to issue an order appointing Mr. Chemla for Exela's Request as well, "in order to facilitate the French Authority's approval of Exela's request." *Id.* The Court issued the Orders and Exela's Request on December 7, 2012. D.I. 282, 283, 284.

On December 11, 2012, Exela received certified copies of Exela's Request and subsequently arranged to have the documents translated. The translated documents were received in late-December, between the Christmas and New Year's holidays. On January 9, 2013, counsel sent the documents to the French Authority via Federal Express and the documents were received on January 11, 2013. Since then, counsel has followed up to determine the status of Exela's Request by contacting the French Authority directly, and even contacting Mr. Chemla to request his assistance. Counsel was able to ascertain that the French Authority received the request, forwarded it to the court for review and action, and that counsel would receive a letter when the court made a determination. Counsel for Exela received a letter from the French Authority on March 13 indicating that it could not grant Exela's Request without this Court designating a commissioner to oversee the taking of evidence. Exela's submission to the French Authority, however, contained the Court's December 7 Order appointing Mr. Chemla. Counsel contacted the French Authority on March 14 to clarify this oversight by the French Authority and was instructed to resubmit the Request via facsimile so that the error could be remedied. This morning, Exela resubmitted the Request as instructed. Exela has no reason to believe the letter responding to its Request will not be immediately forthcoming once this error is remedied.

Regarding Exela's efforts to execute its subpoena to BMS US, Plaintiffs again mischaracterize the relevant facts. In response to the subpoena, BMS US objected to producing any documents located outside the United States based on the French Blocking Statute and on grounds that the documents were "more readily available or accessible to Exela through discovery of Cadence and/or Pharmatop." *See, e.g.*, Ex. J at 4 (May 14, 2012 BMS objections and responses to Exela subpoena). BMS US subsequently began a rolling document production and the parties continued to discuss BMS US's objections. Ex. K (July 9, 2012 letter from M.

Defendants' efforts to obtain documents from BMS US pursuant to their subpoena. D.I. 299, Ex. P at 11.

Houston to R. McCormick). BMS US continued to maintain its objection to produce documents located in France—documents that would be relevant for Mr. Drouin's deposition.

In light of BMS US's objections, at least as early as September 27, 2012, Exela asked for Plaintiffs' assistance to obtain the documents from BMS in France. D.I. 299, Ex. S at 2. Exela's understanding was that, [redacted] D.I. 299, Ex. S at 2. With Plaintiffs' assistance obtaining documents, the parties could have submitted a joint request to the French Authority for the deposition and deposed Mr. Drouin months ago. Plaintiffs, however, chose not to expedite the matter and refused to exercise their contractual rights to obtain the documents requested by Exela. For these reasons, and in light of the Court's November 9 Order, Exela explained to Plaintiffs that it would not agree to go forward with Mr. Drouin's deposition until it received a ruling from the French Authority. Exela agreed, however, that once the French Authority acted, the parties should stipulate to a schedule for exchanging expert reports that related to Mr. Drouin's testimony. D.I. 299, Ex. S at 4.

Confusingly, Plaintiffs assert that Exela has not identified "any specific documents that it pursued from BMS," yet in the email attached as Exhibit S to its letter (D.I. 299), a portion of which was highlighted for the Court, Mr. Polk conveyed just that:

> We were informed that BMS has withheld technical documents relating to Perfalgan that are responsive to our discovery requests sent to BMS and responsive to discovery requests sent to the named Plaintiffs' in this case. From what I was told, these are documents that reside in France but may not have been sent to Cadence as part of the technology transfer under the license agreement. We also have seen limited discovery from the BMS Italy facility, which currently makes Ofirmev.
>
> Having never seen this documentation, I cannot tell you exactly what it is. We just know there are responsive technical documents that are being withheld. Suggest you address this topic with BMS counsel, or have Pharmatop's counsel do so pursuant to [redacted]. Presumably, [redacted] Either way, appears that the fastest route to these documents is Pharmatop obtaining [redacted] and then producing them to us in view of the Court finding that the French Blocking Statute is no bar to Pharmatop producing documents in this case.

D.I. 299, Ex. S at 1. Furthermore, Defendants' communication with BMS's counsel regarding the subpoena, on which Plaintiffs' counsel was copied, detailed categories of information that defendants unsuccessfully tried to obtain from BMS US. Ex. M (Oct. 8, 2012 email from R. McCormick to S. Brunner). Ultimately, BMS refused to produce the requested documents without a court order or unless a Hague request was granted. *Id.* Less than a month later, Defendants filed their letter asking the Court to grant the Request, which contained the specific document requests. (D.I. 259).

As set for the above, Exela diligently pursued documents from BMS US, even requesting Plaintiffs to assist due [redacted]. In particular, [redacted] (Ex. L at 27). Nearly six months ago, Exela asked:

> that SCR Pharmatop exercise [redacted] Judge Stark has already ruled that the French Blocking statute is no bar to SCR Pharmatop producing French discovery in this case. As such, we seek the discovery that BMS is withholding pursuant to SCR Pharmatop's rights [redacted]

D.I. 299, Ex. S at 2. Rather than exercising their rights to the requested documents, Plaintiffs forced Exela to seek the documents via the French Authority. Therefore, Plaintiffs' request that the Court revisit its November 9 Order is misplaced. Exela has been equally prejudiced by the inability to obtain discovery of BMS in France, and Plaintiffs' refusal to assist Exela in obtaining the documents has unnecessarily delayed the Drouin deposition. Proceeding with the Drouin deposition before the French Authority acts on Exela's documents requests, however, is unwarranted and prejudicial to Exela, particularly in view of Exela's diligence in pursuing the deposition and the documents, and Plaintiffs' own failure to obtain this discovery based upon their [redacted] Moreover, as the Court noted at the November 9 hearing, due to the limited relevance of Mr. Drouin's testimony, the Court could "put commercial success on its own track" if there was delay in obtaining the documents and deposition testimony. D.I. 299, Ex. P at 5. Therefore, Plaintiffs have suffered no prejudice and their motion should be denied.

Respectfully submitted,

/s/ Adam W. Poff

Adam W. Poff (No. 3990)

Enclosure

cc: All counsel of record (by email)
Clerk of the Court (by hand delivery)